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Nos. 80-2182 and 81-11

In the Supreme Court of the United States

OCTOBER TERM, 1981

INWOOD LABORATORIES, INC., ET AL., PETITIONERS

v.

IVES LABORATORIES, INC.

DARBY DRUG CO., INC., ET AL., PETITIONERS

v.

IVES LABORATORIES, INC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether petitioners violated Section 32 of the Lanham Act by selling generic drugs in capsules identical to those used by respondent and by engaging in comparative price advertising.

TABLE OF CONTENTS

	Page
Interest of the United States	1
Statement	2
Introduction	
1. Market background	2
2. Background of this litigation	5
The Parties and the Complaint	5
Proceedings Below	7
1. The motion for a preliminary injunction	7
2. The trial and second appeal	8
3. The remedy ordered in the district court	12
Introduction and summary of argument	13
Argument	16
I. The court of appeals erred in finding contributory infringement of respondents' tradename "cyclospasmol" on the basis of petitioners' capsule color copying and comparative advertisements	16
A. A finding of contributory infringement under Section 32 of the Lanham Act requires proof of guilty knowledge	16
B. Petitioners are not responsible for the isolated acts of "palming off" disclosed by this record	19
C. The court of appeals' ruling could chill truthful advertising and legitimate competitive behavior	22
II. This case should be remanded so that the court of appeals can review the district court's ruling with respect to section 43(a) of the Lanham Act	24

Argument (continued) Page

A. Colors with secondary meaning convey significant information to consumers 26

B. Claims that colors have functional value require careful scrutiny 28

III. The district court's judgment grants overly broad and inappropriate relief 32

TABLE OF AUTHORITIES

Cases:

Bates v. *State Bar of Arizona*, 433 U.S. 350 23
Bose Corp. v. *Linear Design Labs, Inc.*, 467 F.2d 304 31
Carl Zeiss Stiftung v. *VEB Carl Zeiss Jena*, 433 F.2d 686, cert. denied, 403 U.S. 905 31
Champion Plug Co. v. *Sanders*, 331 U.S. 125 31
Coca-Cola Co. v. *Snow Crest Beverages, Inc.*, 64 F. Supp. 980, *aff'd*, 162 F.2d 280, *cert. denied*, 332 U.S. 809 ..... 14, 16-17, 18, 20, 23
Compco Corp. v. *Day-Brite Lighting, Inc.*, 376 U.S. 234 8
Ernst & Ernst v. *Hochfelder*, 425 U.S. 185 19
Famolare, Inc. v. *Melville Corp.*, 472 F. Supp. 738.. 18
Fisher Stoves, Inc. v. *All Nighter Stove Works, Inc.*, 626 F.2d 193 25
Fleischman Distilling Corp. v. *Maier Brewing Co.*, 314 F.2d 149 8
FTC v. *Winsted Hosiery Co.*, 258 U.S. 483 ..... 17, 20
Hartford-Empire Co. v. *United States*, 323 U.S. 386 ..... 15, 31
Keebler Co. v. *Rovira Biscuit Corp.*, 624 F.2d 366.. 25
Kellogg Co. v. *National Biscuit Co.*, 305 U.S. 111 ..... 8, 10, 14, 15, 23-24, 31
National Society of Professional Engineers v. *United States*, 435 U.S. 679 23
NuGrape Co. v. *Glazier*, 22 F.2d 596 18
O'Day Corp. v. *Talman Corp.*, 310 F.2d 623, cert. denied, 372 U.S. 977 25
Pagliero v. *Wallace China Co.*, 198 F.2d 339 8

Cases (continued) Page

Saxlehner v. *Wagner*, 216 U.S. 375 22
Sears, Roebuck & Co. v. *Stiffel Co.*, 376 U.S. 225.... 8
SK&F, Co. v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 25
Smith, Kline & French Laboratories v. *Clark & Clark*, 157 F.2d 725 18
Truck Equipment Service Co. v. *Fruehauf Corp.*, 536 F.2d 1210, cert. denied, 429 U.S. 861 25
United States v. *United States Gypsum Co.*, 438 U.S. 422 24
Upjohn Co. v. *Schwartz*, 246 F.2d 254 18
Vibrant Sales, Inc. v. *New Body Boutique, Inc.*, 652 F.2d 299 25
Virginia Pharmacy Board v. *Virginia Consumer Council*, 425 U.S. 748 ..... 4, 23, 29
Vuitton et Fils S.A. v. *J. Young Enterprises, Inc.*, 644 F.2d 769 25
West Point Manufacturing Co. v. *Detroit Stamping Co.*, 222 F.2d 581, cert. denied, 350 U.S. 840..... 25
William R. Warner & Co. v. *Eli Lilly & Co.*, 265 U.S. 526 ..... 15, 17-18, 20, 31

Constitution, statutes and rule:

Constitution of the United States:
First Amendment 23
Act of Oct. 9, 1962, Pub. L. No. 87-772, Section 17, 76 Stat. 773 20
Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* 2
Lanham Act, 15 U.S.C. 1051 *et seq.* 1
Section 32, 15 U.S.C. 1114..7, 9, 13, 14, 15, 16, 19, 24
Section 32(1)(b), 15 U.S.C. 1114(1)(b) 31
Section 35, 15 U.S.C. 1117 31
Section 43(a), 15 U.S.C. 1125(a) ..... *passim*
Section 45, 15 U.S.C. 1127 19
N.Y. Gen. Bus. Law § 368-d (McKinney 1968)..... 7
N.Y. Educ. Law (McKinney Supp. 1981) 4
§ 6810.6(a) 4
§ 6815.2.j 4
§ 6816-a.1 4
Fed. R. Civ. P. 52(a) 14

Miscellaneous: Page

Competition in the Drug Industry: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce, 97th Cong., 1st Sess. (1981) 4
Congressional Research Service, 92d Cong., 2d Sess., *Competitive Problems in the Drug Industry: A Summary Analysis and Discussion of Issues Based on Hearings Before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business* (Comm. Print 1972) 2, 3, 22
Cooper *Trademark Aspects of Pharmaceutical Product Design*, 70 Trademark Rep. 1 (1980) 27
FDC Reports (Mar. 9, 1981) 2
46 Fed. Reg. 27396 (1981) 5
Goldberg, "MAC's Impact: What's Really Ahead for the Drug Field?" *Drug Topics* (Dec. 1, 1975) 4
McClure, *Trademarks and Unfair Competition: A Critical History of Legal Thought*, 69 Trademark Rep. 305 (1979) 27
II *Restatement of Torts* (1934) 18
III *Restatment of Torts* (1938) 18
S. Rep. No. 1333, 79th Cong., 2d Sess. (1946) 19, 27
S. Rep. No. 2107, 87th Cong., 2d Sess. (1962) 20
SRI International, *Pharmaceutical Industry Perspectives: A U.S. Generics Breakthough?* (May 1980) 32
M. Statman, *The Effect of Patent Expiration on the Market Position of Drugs* (Nov. 15-16, 1979) 4

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INTEREST OF THE UNITED STATES

This case raises important questions concerning the interrelationship of federal competition and trademark policies in the marketing of prescription drugs. The United States enforces federal competition policy, as expressed in the antitrust and patent laws. It also is responsible for enforcement of the Lanham Act, 15 U.S.C. 1051 *et seq.*, which prohibits trademark infringement

and certain forms of unfair competition. Moreover, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, the United States regulates aspects of the prescription drug industry, and under other federal statutes it administers and subsidizes various health care activities. As a result of these responsibilities, the United States has a particular interest in interpretations of trademark law that define fair and open competition in the prescription drug industry.

STATEMENT

Introduction

1. *Market background.* The controversy in this case focuses on the marketing and distribution of brand name and generic prescription drugs. The retail prescription drug market [1] is unusual because the article purchased is not selected by the consumer in the first instance, but by his physician. State laws require pharmacists to follow physicians' directions in filling prescriptions.[2] As a result, manufacturers of prescription drugs direct their promotional activities primarily to physicians. This is done through advertising in professional magazines and by employing "detail men" to visit doctors' offices, ex-

[1] The prescription drug market can be divided into two submarkets. The "retail" market comprises the distribution of drugs to individual consumers through pharmacies. The "institutional" market comprises the sale of drugs to hospitals and government or other agencies for distribution to patients. The controversy in this case arose from retail sales, although the relief granted covers institutional sales as well. The prescription drug industry as a whole had sales of roughly $8.5 billion in 1980. See *FDC Reports* (Mar. 9, 1981), at 15.

[2] "The physician, therefore, is the key individual in the decision-making process involving the sale of prescription pharmaceuticals." Congressional Research Service, 92d Cong., 2d Sess., *Competitive Problems in the Drug Industry: A Summary Analysis and Discussion of Issues Based on Hearings Before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business* 3 (Comm. Print 1972).

plain products, and distribute free samples.[3] These promotional activities are in fact the principal source of information on new drugs for most doctors.[4] Secondary promotional efforts are directed to pharmacists to insure that they stock any products a doctor might prescribe. Little, if any, advertising is directed to consumers.

Historically, these promotional activities have been carried out almost exclusively by the larger "brand name" drug manufacturers, which also invest heavily in research and development of new drugs.[5] The major form of rivalry among these firms is product differentiation, carried out by the development of patentable products[6] and a strong emphasis on the use of tradenames rather than generic names in the promotion of prescription drugs.[7] This marketing technique, operating in a context in which physicians lack readily available information on the relative quality and prices of drugs,[8] has resulted in 90% of all prescriptions being written by brand name.[9] Price variations on therapeutically similar drugs indicate that manufacturers retain significant market power after the expiration of patents on their prescription drugs.[10]

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[3] *Id.* at 5-6, 36, 54-55.

[4] *Id.* at 54-56.

[5] *Id.* at 18-19, 54.

[6] *Id.* at 27-29.

[7] *Id.* at 39-40. Even with respect to drugs not protected by a patent, a brand name manufacturer such as Wyeth Laboratories does not promote, for example, "Wyeth's meprobamate" as superior to the thirty other brands of meprobamate. Rather, it promotes its product by its own brand name, "Equanil", and claims that it is superior to all other mild tranquilizers. *Id.* at 42-43.

[8] *Id.* at 54-59. As of the late 1960's, there were "about 4,000 different dosage forms of some 1,200 single drug entities and about 6,000 drug combination products." *Id.* at 4 (footnote omitted).

[9] *Id.* at 41, 45. In addition, most state drug substitution laws are premised on the assumption that prescriptions will refer to the brand name. See notes 11, 28, *infra*.

[10] In 1970, for example, five brand name producers sold the drug reserpine under five different trade names (Serpasil, Sandril,

In recent years the industry has undergone several changes, each of which has contributed to increased competition in the marketing of prescription drugs. First, nearly all states now have enacted drug substitution laws under which pharmacists may, under certain conditions, dispense a lower-priced generic drug even if the doctor's prescription specifies, as most do, a brand name.[11] Second, in *Virginia Pharmacy Board* v. *Virginia Consumer Council*, 425 U.S. 748 (1976), this Court struck down state-imposed restrictions on truthful advertising of retail drug prices as violative of the First Amendment. Third, the patents are or soon will be expiring on a wide variety of frequently prescribed drugs.[12] And fourth, the Food and Drug Administration has eased

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Serfin, Eskaserp, and Reserpoid). The drugs with these trade names had retail list prices ranging from $9.12 to $46.00 per thousand 0.25 mg. tablets. Eight generic producers sold the same drug with retail list prices ranging from 58 cents to $2.80 per thousand. *Id.* at 9-11. See M. Statman, *The Effect of Patent Expiration on the Market Position of Drugs* 8-13 (Nov. 15-16, 1979) (unpublished study prepared at Rutgers University for the American Enterprise Institute).

[11] *Competition in the Drug Industry: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 97th Cong., 1st Sess. 5 (1981) (*"1981 Hearing"*).

Under the New York law, for example, a doctor's prescription must indicate either "substitution permissible" or "dispense as written" (N.Y. Educ. Law § 6810.6(a) (McKinney Supp. 1981)). If substitution is permitted and the drug is on an approved state list, "[a] pharmacist shall substitute a less expensive [generic] drug product," in which event, he "shall indicate on the label * * * the name and strength of the drug product and its manufacturer unless the prescriber specifically states otherwise." N.Y. Educ. Law § 6816-a.1 (McKinney Supp. 1981); cf. *id.* at § 6815.2.j (McKinney Supp. 1981).

[12] Between 1975 and 1980, the patents expired on 30 of the 100 most frequently prescribed drugs. Goldberg, "MAC's Impact: What's Really Ahead for the Drug Field? *Drug Topics* (Dec. 1, 1975), at 22. The patents on four more drugs, including Valium (the most commonly prescribed drug), will expire in 1984 and 1985. *1981 Hearing*, *supra* note 11, at 8.

requirements for the approval of generic drugs for sale (see 46 Fed. Reg. 27396 (1981)) and has formulated and published standards on drug equivalencies (see 21 C.F.R. 20.117(2)(3)).

2. *Background of this litigation.* The controversy in this case arises from the manner in which brand name and generic prescription drugs are commonly packaged for sale. Manufacturers or wholesalers sell drugs to pharmacists in bulk containers labeled with the manufacturer's name. The consumer, however, rarely sees that container. When a pharmacist fills a prescription, he transfers the prescribed number of pills or capsules from the manufacturer's container to his own, and types out his own label, which sets forth the identity of the drug, the dosage, the doctor's instructions, and, in certain circumstances under New York law, the manufacturer's name (see note 11, *supra*). Unless the state law is followed to the letter, this practice necessarily leaves room for various improper acts by pharmacists, ranging from fraudulent substitution to inadvertent trademark infringement, which, so long as the different brands are nearly identical in appearance, will rarely be noticed by the consumer. The issues in this case are whether manufacturers and wholesalers are liable for such deceptive acts by pharmacists and, if so, whether and to what extent they have an affirmative duty to prevent resulting consumer confusion.

The Parties and the Complaint

1. The drug cyclandelate, a white powder, is a peripheral vasodilator claimed to produce an increase in blood flow in patients with certain vascular diseases (C.A. App. 164a-165a).[13] The drug is sold by prescription only, and is generally taken daily for long-term therapy, primarily by the elderly (C.A. App. 237a).

For some years the respondent, Ives Laboratories, Inc. ("Ives"), has sold this drug under the registered trade-

[13] "C.A. App." refers to the joint appendix in the court of appeals. "Pet. App." refers to the appendix to the petition for certiorari in No. 80-2182.

mark CYCLOSPASMOL. Until the patent on cyclandelate expired in 1972, Ives had the exclusive right to make and sell the drug in the United States (C.A. App. 164a, 165a). Ives has marketed CYCLOSPASMOL in 200 mg. dosages in a pale blue capsule imprinted "Ives 4124" since 1962, and in 400 mg. dosages in red and blue capsules imprinted "Ives 4148" since 1975 (C.A. App. 213a-214a).

The manufacturer petitioners [14] purchase cyclandelate powder and empty capsules and assemble the product for sale to wholesalers and hospitals (C.A. App. 166a). The wholesaler petitioners sell primarily to pharmacies and physicians (*ibid.*). It has been the prevailing practice of some generic drug manufacturers for more than 20 years to market their products in the same form and color as the leading brand name manufacturers (C.A. App. 765a). In this case, all petitioners intentionally sold 200 mg. and 400 mg. capsules of cyclandelate in colors identical to Ives' CYCLOSPASMOL (C.A. App. 167a).[15] These capsules were sold in bulk containers that correctly identified the manufacturer.

The manufacturer petitioners truthfully describe their generic product to wholesalers and hospitals as "similar" or "comparable" or "equivalent" to CYCLOSPASMOL

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[14] The petitioners in No. 80-2182, Premo Pharmaceutical Laboratories, Inc. ("Premo") and Inwood Laboratories, Inc. ("Inwood"), are both manufacturers. Inwood also sells to some retail pharmacies (C.A. App. 166a). Of the additional petitioners in No. 81-11, MD Pharmaceutical Co. is a manufacturer, and Darby Drug Co., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co. ("Sherry") are wholesalers (*ibid.*). The district court in this case entered an injunction barring Sherry from using the name "Spasmol" (Pet. App. 70a); that injunction is not presented for review in this Court.

[15] Since the commencement of this litigation, Premo has begun to imprint the word "Premo" on its capsules and Inwood has imprinted "NDC 258" on its capsules. The imprints are, by necessity, very small (C.A. App. 166a).

(C.A. App. 60e-116e).[16] They also use catalogs which specify the difference in price between their generic product and CYCLOSPASMOL, which is referred to by name.[17]

2. Ives' complaint, filed in the United States District Court for the Eastern District of New York, alleges three causes of action that are relevant here: (1) that petitioners violated Section 32 of the Lanham Act, 15 U.S.C. 1114, because their look-alike capsules provide "an instrument of fraud" to retail druggists who use Ives' trademark CYCLOSPASMOL in selling capsules not manufactured by it (C.A. App. 18a); (2) that petitioners violated Section 43(a) of the Lanham Act, 15 U.S.C. 1125(a), because they used a false designation of origin in distributing their products (C.A. App. 17a); and (3) that petitioners' practices violated New York's unfair competition laws, N.Y. Gen. Bus. Law § 368-d (McKinney 1968) (C.A. App. 20a). The primary relief sought is an injunction prohibiting petitioners from marketing cyclandelate in capsules with colors identical to the colors used by Ives (*id.* at 21a).

Proceedings Below

1. *The motion for a preliminary injunction.* The district court denied Ives' motion for a preliminary injunction (Pet. App. 1a-27a), and the court of appeals affirmed (*id.* at 28a-53a). The court of appeals concluded, however, that Ives would be entitled to relief under Section 32 of the Lanham Act if it could prove, following a trial on the merits, that petitioners "suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or continued to sell capsules containing the generic drug which

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[16] Petitioners' products contain the same active ingredient as CYCLOSPASMOL. Ives has abandoned its allegations of therapeutic differences between CYCLOSPASMOL and petitioners' products (Pet. App. 62a).

[17] See C.A. App. 51e-116e.

facilitated this to a druggist whom [they] knew or had reason to know was engaging in the practices just described" (*id.* at 35a).

In addressing Ives' Section 43(a) claim, the court of appeals concluded that limitations on state unfair competition laws, established in *Sears, Roebuck & Co.* v. *Stiffel* Co., 376 U.S. 225 (1964), and *Compco Corp.* v. *Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964), were inapplicable to a claim under federal law (Pet. App. 47a-48a). The court also concluded that copying a nonfunctional feature,[18] which had an established secondary meaning,[19] would constitute a violation of Section 43(a) (Pet. App. 48a-49a). Finding the functionality of capsule color to be "fairly arguable" on the record before it (Pet. App. 50a), however, the court of appeals deferred to the district court's factual determination that the evidence did not warrant a preliminary injunction. The court refused to hold that colors should automatically be denied protection under Section 43(a). Instead, it left for trial the questions whether the capsule colors in this case are functional or have a secondary meaning (*id.* at 50a-51a).

2. *The Trial and Second Appeal.* Following a trial in which more than thirty witnesses testified, the district

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[18] " 'Non-functional' " features are those " 'primarily adopted for purposes of identification and individuality and, hence, unrelated to basic consumer demands in connection with the product'." Pet. App. 49a, quoting *Pagliero* v. *Wallace China Co.*, 198 F.2d 339, 343 (9th Cir. 1952). A feature is " 'functional' " for trademark law purposes if it is an " 'important ingredient in the commercial success of the product'." Pet. App. 49a. See *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111, 122 (1938).

[19] "Secondary meaning" exists when a particular feature connotes to consumers a product from a unique source. To establish secondary meaning, it is not necessary to show that consumers actually know the name of the source. It is only necessary to show that consumers reasonably believe that products bearing the feature in question derive from the same source as other products bearing that feature. See, *e.g.*, *Kellogg Co.* v. *National Biscuit Co.*, *supra*, 305 U.S. at 118; *Fleischmann Distilling Corp.* v. *Maier Brewing Co.*, 314 F.2d 149 (9th Cir. 1963).

court dismissed Ives' claims in their entirety (Pet. App. 54a-70a). The district court concluded that Ives once again had failed to prove any contributory trademark infringement in violation of Section 32—*i.e.*, Ives failed to prove that petitioners suggested "even by implication, that pharmacists fill bottles with the generic drug cyclandelate and apply the trademark CYCLOSPASMOL. Nor did Ives show that [petitioners] continued to sell the generic drug to pharmacists who [petitioners] knew or had reason to know were engaging in such a practice" (Pet. App. 59a). Since petitioners did not "detail" their products through sales representatives, any implied or explicit suggestion to misuse the mark CYCLOSPASMOL could stem only from their catalogs and promotional material (C.A. App. 51e-116e), which the court found "cannot fairly be read as suggesting to druggists that they affix Ives' mark to bottles containing [petitioners'] capsules" (Pet. App. 59a). Similarly, it concluded that the evidence was insufficient to establish that petitioners knew of wide-spread infringement by pharmacists because (1) mislabeling did not occur with significant frequency and (2) to the extent that mislabeling did occur, it was due primarily to a misunderstanding by druggists of the precise requirement of the New York Drug Substitution Law (Pet. App. 59a-60a).[20]

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[20] At trial, Ives offered evidence of two types of violations by pharmacists. First, there were instances of illegal substitution accompanied by mislabeling. In those instances, doctors had prescribed CYCLOSPASMOL, to be dispensed as written, and the pharmacists illegally substituted a generic product and mislabeled it as CYCLOSPASMOL. Ives proved only 15 such occurrences. Its evidence derived from test purchases from pharmacists "selected from shops at the suggestion of employees of Ives because they thought these pharmacies might be making illegal substitutions in filling prescriptions for CYCLOSPASMOL" (C.A. App. 165a, 170a-171a, 833a; Pet. App. 36a).

Second, there were instances of simple mislabeling. Of a sample of 83 pharmacists who filled prescriptions permitting substitution, 35 pharmacists dispensed generic cyclandelate. Of these 35, only ten used the word "CYCLOSPASMOL" on the label (C.A. App. 536e). Of those ten, however, five modified the trademark with some form

Addressing Ives' Section 43(a) claim, the district court held that capsule color copying could be barred only if Ives proved that its colors had acquired a secondary meaning and that they were not functional (Pet. App. 62a). It found that the colors were functional for several reasons. First, the court found that because many patients—particularly users of cyclandelate—associate the appearance of their medication with its therapeutic effect, some will refuse drugs with different coloring while others, although accepting the new colored drugs, suffer "considerable anxiety and confusion by the change." *Id.* at 63a. Second, the court found that patients frequently commingle their drugs in a single container, relying only on color to follow their doctor's instructions. *Ibid.* Third, the court found that color was useful in certain emergency situations in identifying drug overdoses. *Ibid.* Finally, the functional aspects of color were demonstrated by the insistence of some hospitals, pharmacies, and wholesalers on receiving drugs of the same color in order to minimize administrative confusion within those organizations. *Id.* at 63a-64a.

Even assuming capsule color to be nonfunctional, the district court also found that Ives had failed to establish secondary meaning in accordance with *Kellogg Co.* v. *National Biscuit Co.*, *supra*, 305 U.S. at 118. It credited the views of several doctors who testified that "patients do not associate the appearance of a drug capsule with the manufacturer or other source but with the drug's effect on the patient's disability" (Pet. App. 65a). The court also found that Ives' survey, which attempted to show that patients associate Ives' capsule colors with CYCLOSPASMOL, was wholly inadequate to establish secondary meaning. The court concluded that the survey was significant not because many patients identified colored cap-

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of the word "generic." And nine of the ten responded to an inquiry whether they had the generic drug in stock by truthfully stating that the prescription had been filled with a generic product. Only one pharmacist charged the brand name price for the generic drug (C.A. App. 942e-976e; Pet. App. 60a).

sules as CYCLOSPASMOL, but because so few patients were able to do so (Pet. App. 66a).[21] Moreover, the court found that even among those patients who did recall the word CYCLOSPASMOL, the survey did not show that patients associated the trademark with a single manufacturer as opposed to the therapeutic qualities of cyclandelate. *Id.* at 66a-67a.[22]

On appeal, a divided panel of the court of appeals reversed, concluding that "the undisputed evidence establishes a violation of § 32" (Pet. App. 74a-75a).[23] The court found the evidence of pharmacist mislabeling to be more significant than did the trial court (*id.* at 81a-82a). The majority also took judicial notice of the issuance of six indictments against druggists in the metropolitan New York area for illegal substitution in violation of state law (*id.* at 84a).[24] While acknowledging that it should not prejudge the guilt or innocence of the pharmacists in those cases, the court nevertheless found these indictments to be sufficient to show "that illegal substitu-

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[21] This survey showed that approximately one-third of those patients taking CYCLOSPASMOL did not recall the name without prompting and another one-third of the patients could not even recognize the word among a group of ten wholly dissimilar trade names. C.A. App. 139e-152e, 372e, 529e.

[22] The district court found Ives' state law claim to be equally without merit. The court concluded that the policies of New York's unfair competition law, which protects consumers from deception, must be weighed against the policies of New York's drug substitution law, which encourages generic drug use. After balancing these conflicting public policies, the court dismissed Ives' state law claim. Pet. App. 69a-70a.

[23] In view of its holding that petitioners violated Section 32, the court of appeals declined to express any view on the claims brought under Section 43(a) or under New York's unfair competition laws. Pet. App. 75a.

[24] These indictments were returned after the trial in this case and were not brought to the attention of the district court. New York State has 15,000 pharmacists and at least 3,000 pharmacies (C.A. App. 766a, 537e-538e; see Pet. App. 89a).

tion and mislabeling in New York are neither *de minimis* nor inadvertent" (*id.* at 83a).

The court also dismissed petitioners' functionality arguments as "unconvincing." The court expressed the belief that anxiety and confusion associated with changes in capsule color are minimal and easily "cured by explaining the change to the patient," and noted the lack of patient testimony to the contrary (Pet. App. 85a). It further reasoned from this premise that, because no functional justification exists for duplicating capsule color, "the inference is inescapable that [petitioners'] use of identically-colored, shaped and sized capsules was in anticipation that they would successfully capitalize upon public acceptance of CYCLOSPASMOL by reason of the fact that at least a substantial number of druggists would either substitute the generic product illegally or mislabel it as CYCLOSPASMOL" (*ibid.*).

Judge Mulligan dissented. He concluded that Ives' evidence was totally inadequate to show widespread substitution or trademark infringement by pharmacists, and certainly was insufficient to show that the petitioners knew or had reason to know of such practices (Pet. App. 87a-89a). He also emphasized that petitioners' juxtaposition of brand and generic names in catalogs was a common and necessary trade practice and that the district court's finding of functionality was not clearly erroneous (*id.* at 90a-91a).

3. *The remedy ordered in the district court.* On remand, the district court held that it was constrained by the court of appeals' mandate to enjoin petitioners' use of Ives' colors for generic cyclandelate (Pet. App. 98a). Moreover, since the court of appeals' decision implied that an intentional violation had occurred, the district court concluded that it must allow Ives to recover damages as well as any profits earned by petitioners through their unlawful actions (*id.* at 100a).

INTRODUCTION AND SUMMARY OF ARGUMENT

This case raises important questions concerning the proper interpretation of the Lanham Act. It involves the delicate interplay between two public policies—one favoring competitive product imitation, the other favoring the use of trade symbols to identify source or origin. Both of these policies seek to promote fair and efficient competition. Trademark law is premised on the belief that manufacturers should have the ability to identify products as their own so as to benefit from favorable customer experience; else they will have little incentive to invest in product quality features as a means of gaining consumer recognition. However, if new entrants are barred from using features which have value to consumers—other than as identifications of source—then those firms will be unduly hampered in their efforts to engage in the competitive process. For the reasons set forth below, we submit that the court of appeals failed to balance these factors correctly, and thus erred in finding deliberate contributory infringement under Section 32 of the Lanham Act.

I.

Analysis of the doctrine of contributory infringement, recognized under Section 32 of the Lanham Act, requires a balancing of the procompetitive effect of trademarks in identifying products for consumers and the anticompetitive effect of raising barriers to market entry by forbidding imitation. As a rule of vicarious liability, contributory infringement holds a manufacturer responsible for illegal acts committed by his customers—or by others more remote in the distribution chain—over whom he may have little direct control. It does not, however, establish a regime of strict liability. Under the standards enunciated by Judge Friendly in the first appeal in this case, and nominally applied by the majority in the second appeal, an essential element of contributory infringement under Section 32 is a showing of active inducement or knowledge of wrongdoing. This rule, requiring a guilty state of mind, has a sound basis in the common law antecedents of the Lanham Act.

The state of mind requirement is not merely a rule of fairness: it serves an essential public policy. No legitimate competitive policies are impaired by requiring manufacturers to refrain from *actively* encouraging trademark infringement, or to refrain from selling to individual customers they know or have reason to know are engaged in such illegal practices. Accordingly, in these limited circumstances, the public interest in an efficient competitive system is best served by requiring manufacturers to take reasonable remedial steps, such as differentiating their product or monitoring their customers. On the other hand, where, as here, only a few unscrupulous retailers out of many are engaged in trademark violations, the public interest balance is quite different. In such a case, the cost of barring imitation outweighs the marginal benefit to trademark interests. As this Court noted in an analogous context in *Kellogg Co.* v. *National Biscuit Co., supra*, 305 U.S. at 121, the intent of the law is not "to insure that every purchaser will know * * * the maker," but rather to insure the use of "reasonable means to prevent confusion." Such "reasonable means" must be proportionate to the magnitude of the problem and consistent with the right to compete.

The court of appeals did not properly weigh these countervailing interests under Section 32 and, accordingly, erred on the side of overdeterrence. The evidence showed only isolated instances of unambiguously deliberate infringement by pharmacists. The record here was far less compelling than in *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F. Supp. 980 (D. Mass. 1946), aff'd, 162 F.2d 280 (1st Cir.), cert. denied, 332 U.S. 809 (1947), where no violation was found. Moreover, on the factual issue of functionality, disputed at trial with sharp evidentiary conflicts, the court of appeals gave insufficient deference to the findings of the district court. See Fed. R. Civ. P. 52(a).

II.

Although the court of appeals did not reach respondent's Section 43(a) claims, it is that provision, rather

than Section 32, which is at the heart of the present controversy. In our view, the fundamental issue in this case is whether capsule color imitation itself constitutes a misrepresentation as to source or origin. The trademark infringement issue decided by the court of appeals is merely peripheral to this more fundamental question. In the event that the holding of the court of appeals under Section 32 is reversed and the case is remanded for consideration of respondent's Section 43(a) claims, it would be appropriate for this Court to establish guidelines for the lower courts. Those guidelines can be framed in a manner that reflects a proper balancing of the public interests involved in this case.

It may well be that the unusual aspects of the prescription drug market—a market in which manufacturers do not address themselves through advertising or promotion to the ultimate consumer—will make it more difficult to establish product and source identity than in other markets. Accordingly, it is essential to avoid articulating standards in this context that would make it unduly difficult for manufacturers in other fields to reap legitimate rewards for producing a product that has strong consumer recognition.

III.

In any event, the injunctive and monetary relief awarded by the district court are far more expansive than the record warrants. See *Hartford-Empire Co.* v. *United States*, 323 U.S. 386 (1945); *Kellogg Co.* v. *National Biscuit Co., supra; William R. Warner & Co.* v. *Eli Lilly & Co.*, 265 U.S. 526 (1924). The record in this case fails to support an injunction barring petitioners from marketing their products in blue and blue-red capsules identical to those used by Ives. In most instances, proper labeling is sufficient to prevent consumer confusion (see *Kellogg Co.* v. *National Biscuit Co., supra*). Even if, as found by the district court, labeling individual capsules will not avoid potential confusion, there may exist far less restrictive alternatives than a total ban on color imitation.

ARGUMENT

I. THE COURT OF APPEALS ERRED IN FINDING CONTRIBUTORY INFRINGEMENT OF RESPONDENT'S TRADENAME "CYCLOSPASMOL" ON THE BASIS OF PETITIONERS' CAPSULE COLOR COPYING AND COMPARATIVE ADVERTISEMENTS

A. A finding of contributory infringement under Section 32 of the Lanham Act requires proof of guilty knowledge

The legal standard for contributory infringement nominally applied by the court below is that "a manufacturer or wholesaler would be liable under § 32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described" (Pet. App. 78a, quoting Judge Friendly's earlier opinion in this case (emphasis omitted)). While that articulation is generally correct, it fails to highlight the importance of the state of mind requirement in contributory infringement cases. And in any event, the court of appeals erred in applying that standard to the record in this case.

Although Section 32 creates strict liability for persons who actually infringe a trademark, the doctrine of contributory infringement is a judicial construction based on the common law principle that a person may be held vicariously liable for the trademark infringement of another person only upon a showing of a guilty state of mind. Judge Friendly's reference (Pet. App. 35a) to *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F. Supp. 980, 989 (D. Mass. 1946), indicates that the Second Circuit recognizes that a state of mind requirement exists in actions for contributory infringement.

In the *Snow Crest* case, bartenders had used Snow Crest's cola beverage instead of Coca-Cola's beverage in

mixed drinks. Snow Crest's manufacture of a product identical in appearance to that of Coca-Cola, it was claimed, constituted contributory infringement. Judge Wyzanski rejected this claim, noting that the supplier would not be liable unless he had "knowledge that the [bartenders] will or can reasonably be expected to commit a tort with the supplied instrument." 64 F. Supp. at 989. He observed, moreover, that "any man of common sense knows that in any line of business * * * there are some unscrupulous persons who, when it is to their financial advantage to do so, will palm off on customers a different product from that ordered by the customer" (*id.* at 988-989). This, however, does not establish contributory infringement. There must be more—either active encouragement of infringement or continued sales to particular customers whom the manufacturer knows or should know are engaged in improper "palm[ing] off." *Id.* at 989.[25]

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[25] "Palming off" refers to deliberate misrepresentation of the source of a product, as, for example, through misapplication of a trademark. In the present case, the district court found that instances of trademark misapplication were inadvertent infringements resulting from pharmacists' failure to understand statutory labeling requirements. See Pet. App. 60a.

This Court has referred to the state of mind requirement in cases involving "palming off" by customers of manufacturers. For example, in *FTC* v. *Winsted Hosiery Co.*, 258 U.S. 483, 493 (1922), a case arising under Section 5 of the FTC Act, Justice Brandeis stated that the false labels on respondent's products were "calculated to deceive and do in fact deceive a substantial portion of the purchasing public." In *William R. Warner & Co.* v. *Eli Lilly & Co.*, *supra*, 265 U.S. at 530, a private unfair competition case, the Court observed that "some of petitioner's salesmen suggested that, without danger of detection, prescriptions and orders for Coco-Quinine could be filled by substituting Quin-Coco. More often, however, the feasibility of such a course was brought to the mind of the druggist by pointing out the identity of the two preparations and the enhanced profit to be made by selling Quin-Coco because of its lower price." In instances where it was found that the defendant's agents had "induced the substitution, either in direct terms or by suggestion or insinuation," the Court held that "[t]he wrong was in

In articulating this standard, Judge Wyzanski relied in substantial part on long-established common law principles of vicarious liability, drawing on such sources as the *Restatement of Torts*. 64 F.Supp. at 989. The provisions of the *Restatement* relied on by Judge Wyzanski fully support the rule that he applied.[26]

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designedly enabling the dealers to palm off the preparation as that of the respondent." *Ibid.* (citations omitted). The lower courts have adopted a similar rule requiring active inducement in cases involving claims of wrongful product imitation. See, *e.g.*, *Smith, Kline & French Laboratories* v. *Clark & Clark*, 157 F.2d 725, 731 (3d Cir. 1946); *Upjohn Co.* v. *Schwartz*, 246 F.2d 254 (2d Cir. 1957); *NuGrape Co.* v. *Glazier*, 22 F.2d 596 (5th Cir. 1927); *Famolare, Inc.* v. *Melville Corp.*, 472 F. Supp. 738, 746 (D. Hawaii 1979).

[26] Section 714 provides (III *Restatement of Torts* 551 (1938)):

> One fraudulently markets his goods as those of another if, though making no misrepresentation himself, he intentionally induces his purchasers so to market them.

Section 302, Comment M, provides (II *Restatement of Torts* 821-822 (1934)):

> The actor is required to realize the likelihood of intentional intermeddling only if he creates a situation or does an act, which affords a temptation to, or an opportunity for, intermeddling by a person or class of persons whom he knows or should know to be peculiarly likely to do so. Thus, if the actor's conduct is intended or likely to create a situation which may do harm if third persons meddle with it, in a place which he should know is likely to be frequented by children without their parents, the actor should recognize the situation as dangerous, although it would be sufficiently safe were the place likely to be frequented only by adults * * *.

In addition, see Section 738, illustration 1, which provides (III *Restatement of Torts, supra*, at 619):

> A manufactures and markets goods under the trade name "Manou." B sells similar goods to wholesalers. While not deceiving them, he advises them to sell the goods as the "Manou" brand. He also sends agents to retailers to advise them to do the same. Both the wholesalers and the retailers do offer B's goods for sale as the "Manou" brand. In each instance B infringes A's trade name.

No conduct or state of mind of this sort was proven in the present case.

Such a rule is, moreover, fully consistent with the objectives of the Lanham Act, in which Congress declared its intent to make actionable "the deceptive and misleading use of marks * * *; to prevent * * * unfair competition; [and] to prevent fraud and deception * * * by the use of reproductions, copies, counterfeits, or colorable limitations of registered marks." 15 U.S.C. 1127. See S. Rep. No. 1333, 79th Cong., 2d Sess. 5 (1946). This language hardly suggests that federal judges, in recognizing remedies for "contributory infringement" that are not specifically prescribed by Congress, should dispense with the state of mind requirement traditionally applied at common law. See generally, *Ernst & Ernst* v. *Hochfelder*, 425 U.S. 185 (1976).

The record in this case does not establish the existence of a state of mind sufficient to predicate liability under Section 32. The only evidence on which the court of appeals relied was the fact that some passing off by pharmacists had occurred, that the capsules were identical, and that petitioners had engaged in comparative price advertising and made specific reference to Ives' products. Such evidence is insufficient to establish either that petitioners were actively involved in any deception, or that they sold to particular pharmacists that they knew or should have known were engaged in infringement.

B. Petitioners are not responsible for the isolated acts of "palming off" disclosed by this record

Neither court below found that petitioners made any direct suggestion, orally or in writing, that would induce a pharmacist to infringe the tradename CYCLOSPASMOL.[27] At most, the court of appeals was able to infer

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[27] Violation of Section 32 must be predicated on infringement of the trademark rather than causing confusion as to the origin of the product. Confusion as to origin is the gravamen of a claim under Section 43(a). See pages 24-30, *infra*. The 1962 amendments to the Lanham Act clearly demonstrate this distinction. Section 32 was amended to delete language referring to deception

that capsule color copying and comparative advertising increased the likelihood that some pharmacists would misuse the tradename CYCLOSPASMOL. That conduct is far more innocuous than the conduct considered by this Court in *Winsted* and *William R. Warner*. See note 25, *supra*. And the result reached by the court of appeals in this case cannot be squared with the holding in *Snow Crest*, *supra*, 64 F. Supp. at 988-989.

Similarly, neither court below suggested that petitioners sold their products to specific pharmacies they knew or had reason to know were engaged in passing off. The court inferred the requisite intent or knowledge solely because petitioners could "reasonably anticipate" that "a substantial number of druggists" would engage in illegal conduct (Pet. App. 82a) and because it believed that petitioners "have not offered any persuasive evidence of a legitimate reason" for using look-alike capsules (*id.* at 84a). The former ground rests on the reasoning that was correctly rejected in *Snow Crest*. Absent active inducement or knowledge of a particular customer's propensities, a "defendant's accountability for his customer's wrongful use of [a] product turns on the issue whether a reasonable person in the defendant's position would realize * * * that he himself had created a situation which afforded a temptation to or an opportunity for wrong" (64 F.Supp. at 989.). The record in this case shows no active inducement or irresistible temptation to the honest pharmacist, nor does it show pervasive illegality by pharmacists. Instead, the panel majority substituted its judgment for that of the district court simply because the isolated instances of substitution and mislabeling were, in its view, "neither *de minimis* nor inadvertent" (Pet. App. 83a).[28]

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concerning "source of origin," while similar language was retained in Section 43(a). Act of Oct 9, 1962, Pub. L. No. 87-772, Section 17, 76 Stat. 773. See S. Rep. No. 2107, 87th Cong., 2d Sess 25 (1962).

[28] In fact, the record is consistent with the conclusion of Judge Mulligan and the district court that the pharmacists simply did

The alternative basis for the majority's inference of guilty knowledge, and the apparent key to its finding of contributory infringement, was a summary rejection of the district court's factual finding that the capsule colors had functional value—*i.e.*, the colors served some commercial or competitive purpose other than representing source.[29] Since it did not believe that color copying could have a functional purpose, the majority concluded that petitioners' only possible motive for color copying was to induce or facilitate "palming off." Even if one were to assume nonfunctionality and clear error by the district court on this factual issue, however, the majority's reasoning contains a logical gap. It is quite possible that petitioners, relying on intuition, anecdotal evidence, or

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not understand the statutory labeling requirements. See page 9 & note 20, *supra*. Indeed, the state substitution laws are based on the implicit premise that doctors and pharmacists communicate with each other by reference to tradenames, even in prescribing generic products. It is understandable that pharmacists will attempt to communicate with their customers in the same language (see C.A. App. 1098a-1101a). Under such circumstances, technical and isolated violations of the trademark laws by pharmacists do not support an inference of an intent to defraud, much less knowledge of pharmacists' fraud by the generic manufacturers. Moreover, since only one out of the group of pharmacists surveyed by Ives failed to admit that he was dispensing a generic product and charged the brand name price (see note 20, *supra*), the evidence refutes the court of appeals' conclusion that a significant number of pharmacists are engaged in intentional deception or profiteering.

Even if one were to go beyond existing law and to impute "guilty knowledge" to a manufacturer who knows that some of his customers might "palm off," yet takes no preventive measures, such a rule would be inapplicable here. In the context of the prescription drug industry, inexpensive alternatives may not have been available to generic manufacturers. As the district court found, labeling each capsule would be ineffective to disclose source. Although prepackaging capsules in consumer-size doses might be feasible, there is no sound basis for imputing "guilty knowledge" to a manufacturer simply because he failed to pursue that novel, and potentially costly, alternative.

[29] See page 10, *supra*.

considered business judgment, actually believed, even if erroneously, that the colors were functional—*i.e*, served purposes other than representation of source. Given this possibility—and given the evidence showing the functional aspects of color in this market—the record in this case does not support the court of appeals' inference of bad faith on the part of the generic manufacturers.[30]

C. The court of appeals' ruling could chill truthful advertising and legitimate competitive behavior

Important public policies mandate rejection of claims of contributory infringement based on comparative advertising. The use of another person's tradename in comparative advertising is protected speech. Competitors "have a right to tell the public what they are doing and to get whatever share they can in the popularity of [a given product] by advertising that they are trying to make the same article and think that they succeed. * * * By doing so they are not trying to get the good will of the name, but the good will of the goods." *Saxlehner* v. *Wagner*, 216 U.S. 375, 380-381 (1910). Moreover, the free availability of comparative price information is not merely tolerated, but is central to our competitive econ-

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[30] Indeed, the panel on the earlier appeal had found the issue of functionality to be "fairly arguable." Pet. App. 50a. The generic manufacturers apparently began copying the capsule colors of the brand name manufacturers long before they had any significant retail market. At that time, they were limited primarily to institutional markets. See C.A. App. 765a; Congressional Research Service, 92d Cong., 2d Sess., *Competitive Problems in the Drug Industry: A Summary Analysis and Discussion of Issues Based on Hearings Before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business* 6-7 (Comm. Print 1972). In this context, they would have little incentive to prepare products for the purpose of passing off, since their hospital and government purchasers certainly were well aware of their sources. Moreover, as noted earlier, there was evidence in the record that some hospital and institutional purchasers expressed a preference for color uniformity, and that color served a significant function apart from identifying the source. See page 10, *supra*.

omy. *National Society of Professional Engineers* v. *United States*, 435 U.S. 679, 692-693 (1978). Even with respect to potentially hazardous products, this Court has held that the antitrust laws protect truthful advertising of prices against suppression at the behest of private parties (*id.* at 695-696), and that the First Amendment protects such advertising against undue governmental prohibitions. *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 363-365 (1977); *Virginia Pharmacy Board* v. *Virginia Consumer Council*, 425 U.S. 748, 761-765 (1976). Whatever incidental effect petitioners' truthful advertising may have in increasing the possibility of infringement, to use that advertising as a basis for liability under Section 32 would needlessly impair competition. Since dishonest retailers are fully capable of seeing the opportunities for fraud without referring to comparative advertising (*Snow Crest*, *supra*, 64 F. Supp. at 988-989), the chilling effect of the majority's ruling on legitimate product imitation is not offset by significantly greater compliance with the trademark laws.

It follows from the foregoing that the court of appeals has not properly weighed the relevant interests in this case. To be sure, when pharmacists engage in infringement, their conduct is not to be condoned;[31] but the offending pharmacists are not before this Court. The question in this case is whether the generic manufacturers—who clearly marked their bulk containers with proper indicia of origin and who themselves engaged in no infringement or active inducement—must suffer broad injunctions, disgorgement of profits, and, perhaps, treble damage awards for the isolated misdeeds of a few self-serving retailers. Consistent with this Court's statement in *Kellogg* that the purpose of the law is not "to insure that every purchaser will know * * * the maker,"

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[31] Our national competition policy, as expressed in the Lanham Act and the antitrust laws, promotes fair competition in which sellers have incentives to identify and differentiate their products.

but only to require "every reasonable means to prevent confusion" (305 U.S. at 121), it is a question that, on this record, must be answered in the negative.

In this regard, the Court's admonitions in *United States* v. *United States Gypsum Co.*, 438 U.S. 422 (1978), are pertinent.[32] Where prohibited behavior is "difficult to distinguish from the gray zone of socially acceptable and economically justifiable business conduct," courts should refrain from imposing rules which may result in "over-deterrence" (*id.* at 441). This is true because (*ibid.*; footnote omitted):

> salutary and procompetitive conduct lying close to the borderline of impermissible conduct might be shunned by businessmen who chose to be excessively cautious in the face of uncertainty regarding possible exposure to criminal punishment for even a good-faith error of judgment.

II. THIS CASE SHOULD BE REMANDED SO THAT THE COURT OF APPEALS CAN REVIEW THE DISTRICT COURT'S RULING WITH RESPECT TO SECTION 43(a) OF THE LANHAM ACT

Unlike Section 32, which focuses on misuse of trademarks, Section 43(a) of the Lanham Act contains a more general prohibition of unfair competition—*i.e.*, a prohibition of marketing techniques that create confusion as to source or origin. The court of appeals did not address the Section 43(a) claim in its decision following the trial on the merits in this case. Under Judge Friendly's earlier opinion, however, Ives could not bar capsule color copying unless it proved that the color in question had a "secondary meaning." Thus, Ives was required to prove

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[32] Although the Court limited its holding in *Gypsum* to the criminal antitrust case before it (438 U.S. at 436 n.13), its reasoning is applicable here. This is particularly true of the Court's observation that "where the conduct proscribed is difficult to distinguish from conduct permitted and indeed encouraged, * * * the excessive caution spawned by a regime of strict liability will not necessarily redound to the public's benefit" (*id.* at 442 n.17).

that consumers associated the capsule color with a single source, though the consumers need not be able to identify that single source.[33] Even if it proved "secondary meaning," moreover, Ives could not bar copying if the color had "functional" value, which Judge Friendly defined as value apart from identifying the product with a particular source (Pet. App. 63a-67a). Thus, a defendant could be held liable only if it copied the "nonfunctional" features of another person's product and if, in addition, those features had acquired a "secondary meaning" (*id.* at 48a-49a). This analysis reflects the prevailing rule that a manufacturer must prove secondary meaning, *i.e.*, consumer identification of certain product features with a particular, if unidentified, source, in order to protect those features from imitation.[34]

In the decision here under review, the court of appeals did not reach the issue of secondary meaning. However, it summarily rejected petitioners' evidence of functionality as "unconvincing" (Pet. App. 84a-85a). Because respondents' Section 43(a) claim may be urged as an alternative ground for affirmance in this Court, and because, in any event, the claim must be considered by the court of appeals on remand, we consider it appropriate to briefly discuss that claim.

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[33] See pages 10-11 & note 19, *supra*.

[34] See, *e.g.*, *Fisher Stoves, Inc.* v. *All Nighter Stove Works, Inc.*, 626 F.2d 193, 194-195 (1st Cir. 1980); *Keebler Co.* v. *Rovira Biscuit Corp.*, 624 F.2d 366, 378 (1st Cir. 1980); *O'Day Corp.* v. *Talman Corp.*, 310 F.2d 623, 624-625 & n.2 (1st Cir. 1962), cert. denied, 372 U.S. 977 (1963); *Vibrant Sales, Inc.* v. *New Body Boutique, Inc.*, 652 F.2d 299, 303 (2d Cir. 1981); *SK&F, Co.* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1065 (3d Cir. 1980); *West Point Manufacturing Co.* v. *Detroit Stamping Co.*, 222 F.2d 581, 589-590 (6th Cir.), cert. denied, 350 U.S. 840 (1955); *Truck Equipment Service Co.* v. *Fruehauf Corp.*, 536 F.2d 1210, 1215 (8th Cir.), cert. denied, 429 U.S. 861 (1976); *Vuitton et Fils S.A.* v. *J. Young Enterprises, Inc.*, 644 F.2d 769, 772 (9th Cir. 1981).

A. Colors with secondary meaning convey significant information to consumers

The district court found that Ives had failed to establish that the capsule colors in this case had become publicly identified with a particular source (Pet. App. 64a-67a). In view of the manner in which prescription drugs are marketed, it is not surprising that the district court found that Ives had failed to establish secondary meaning. As the district court noted: "Ives' failure of proof highlights the difficulty of proving secondary meaning to consumers in the prescription drug market" (*id.* at 68a). The promotion of prescription drugs is necessarily directed chiefly to physicians, "[b]ut extensive promotion to physicians does not establish that they have passed along to their patients any message as to source. For that reason, secondary meaning will perhaps be difficult to establish in these prescription drug cases where the patient never sees the manufacturer's packaging" (*id.* at 68a-69a). Indeed, the district court may well have understated the matter, for the color of an item is not a feature to which one necessarily looks for an indication of source, and Ives' evidence suggests that even drug nomenclature is a mystery to most consumers.[35]

It should be recognized, however, that a finding that Ives failed to prove secondary meaning for its capsule colors does not preclude other manufacturers from establishing secondary meaning in specific capsule colors if they are capable of proving the requisite association in

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[35] Ives' sole evidence of secondary meaning was a consumer survey of patients for whom CYCLOSPASMOL had been prescribed. It showed that one-third of the patients spontaneously identified petitioners' capsules as CYCLOSPASMOL, and another third, who had been unable to identify them initially, were able to pick CYCLOSPASMOL from a list of ten dissimilar brand names for various drugs. The final third were unable to identify the capsules even from a list. See note 21, *supra*. That survey, however, did not seek to establish whether the patients recognized that CYCLOSPASMOL was a tradename, or otherwise indicated a source of origin for the drug.

the minds of consumers. As Judge Friendly noted (Pet. App. 50a), earlier cases which rejected, as a matter of law, the concept that secondary meaning may inhere in a color are outdated, and in any event reflect an unawareness of the utility of product differentiation as a means of avoiding consumer confusion.[36] Modern technology is capable of producing myriad colors, shades, and combinations.[37] If drug manufacturers should, in the future, choose to advertise or otherwise establish secondary meaning in specific capsule colors, and those colors are found to be nonfunctional in the context of the particular case, no social policy would be served by denying the manufacturers the protection afforded under Section 43(a) of the Lanham Act.

Moreover, in a case such as this, arising in the prescription drug market, care must be taken to avoid allowing governing legal principles to be distorted by the unusual characteristics of a market in which manufacturers and ultimate consumers are remote from one another. The protections Congress intended under Sec-

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[36] Nonfunctional product features that have acquired a secondary meaning serve the same purpose as trademarks in identifying source to consumers, and in so doing they promote competitive objectives. As Congress noted in passing the Lanham Act (S. Rep. No. 1333, 79th Cong., 2d Sess. 4 (1946)):

> Trade-marks, indeed, are the essence of competition, because they make possible a choice between competing articles by enabling the buyer to distinguish one from the other. Trademarks encourage the maintenance of quality by securing to the producer the benefit of the good reputation which excellence creates. To protect trade-marks, therefore, is to protect the public from deceit, to foster fair competition, and to secure to the business community the advantages of reputation and good will by preventing their diversion from those who have created them to those who have not.

See generally McClure, *Trademarks and Unfair Competition: A Critical History of Legal Thought*, 69 Trademark Rep. 305 (1979).

[37] See Cooper, *Trademark Aspects of Pharmaceutical Product Design*, 70 Trademark Rep. 1, 22-27 (1980).

tion 43(a) should remain fully available to manufacturers in consumer-oriented markets who, by their commercial ingenuity, succeed in investing their products with secondary meaning having informational value to the consuming public.

B. Claims that colors have functional value require careful scrutiny

Should the court of appeals, on remand, set aside the district court's findings on secondary meaning as clearly erroneous, it will then be required to determine that the capsule colors here involved are not functional before it may ban color imitation. As indicated above, the majority opinion simply dismissed the district court's findings of functionality without any analysis. We submit that a more discriminating treatment of this question is called for, particularly in view of the existence in this case of two distinct consumer submarkets: retail and institutional purchasers.

The district court's first finding of functionality was that the colors had commercial significance to individual consumers because the colors had come to symbolize the "therapeutic effects" of the drug cyclandelate. Thus, "some patients may be fearful and offer resistance if their accustomed medicine is dispensed in a different color" (Pet. App. 22a). Deeming color to be functional merely because it allays consumer anxiety, however, is somewhat anomalous. Such analysis is based on the paternalistic notion that, in order to avoid irrational action by consumers, a change in source should be *concealed* from them. We strongly question the propriety of such an approach in an economic system designed to maximize *informed* consumer choice.

Under existing laws, consumers are not allowed to select prescription drugs themselves. If they have a question about the use of a new color capsule for their medicine, their doctors or dispensing pharmacists are available to explain it. The district court's reasoning assumes that consumers are unable to react rationally to such an ex-

planation. That assumption, however, reflects the type of "paternalistic approach" to drug marketing that this Court rejected in *Virginia Pharmacy Board* v. *Virginia Consumer Council*, *supra*, 425 U.S. at 770. As the Court noted in that case, the better assumption is "that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them." *Ibid.*

The danger perceived by the district court is that some consumers might perceive a change in capsule colors to mean that the new medicine is not as effective as the original medicine. But there is no reason to believe, absent clear evidence to the contrary, that any such incorrect impressions cannot be cured readily by doctors or pharmacists responding to patient inquiries. Different colors will often lead consumers to inquire, and they then can make an informed decision. Conversely, unrestricted imitation of capsule colors may interfere with the communication to consumers of information about source of origin. Consequently, we submit that absent any *other* functional effects attributable to capsule color copying, it would be contrary to public policy to allow copying of capsule colors which have attained secondary meaning solely to protect a few persons from making a choice based on irrational anxiety rather than medically significant facts.

The district court did find, however, that capsule color imitation has several functional benefits apart from avoiding consumer anxiety. There was evidence that some patients placed various medicines in a single container and relied on capsule colors to identify the pill they must take at a specific time—*e.g.*, "I take the red one at six o'clock." See C.A. App. 367a-369a. Similarly, there was evidence that when overdose victims are unable to inform physicians of the identity of the drugs taken, capsule colors may help physicians to identify the

drug involved. See *id.* at 1025a-1027a, 1138a-1141a. While reliance on capsule color for these two purposes is far from optimal from the perspective of health care, the test of "functionality" would be satisfied if they were important to a significant group of consumers. On the other hand, color imitation would not be commercially significant, *i.e.*, would not meet the test of functionality, if only a few patients mix their medications in a single container and rely on color to identify medicinal properties. By the same token, there would be little commercial or competitive significance if the identities of drugs taken in overdose situations are ascertained by capsule color only in rare instances. Color should not be deemed functional for the foregoing reasons unless there is evidence that, to obtain such benefits, a significant number of physicians or patients would prefer a medicine because it is dispensed in a particular colored capsule.

The district court's finding of functionality based on resistance by hospitals and retail pharmacies to purchasing drugs in capsules of different colors (Pet. App. 63a-64a) also turns on evidence that is rather sparse. There is evidence that some hospitals would prefer to purchase a generic drug in the same color capsule as the name brand in order to lessen the likelihood of confusion in the dispensing of medication. Compare C.A. App. 1269a-1275a, 1431a, 686e-688e, 706e-707e, 710e, 713e, with 797a, 1034a-1035a, 1145a-1146a, 1332a, 1428a-1434a. Whether such sentiment is widespread is not clear, particularly since hospitals generally do not segregate medicine by capsule color. Similarly, there is little evidence concerning retail pharmacy resistance to purchasing generic drugs in different colored capsules. See *id.* at 1109a-1110a, 747e-749e. It is difficult, on the present record, to gauge how significant a market barrier such sentiment would be or to assess whether resistance from hospitals, wholesalers or retail pharmacies is substantial enough to render color a functional feature.

III. THE DISTRICT COURT'S JUDGMENT GRANTS OVERLY BROAD AND INAPPROPRIATE RELIEF

If, after remand, it is determined that some form of relief is required, that relief should be carefully tailored to meet the circumstances of this case. See, *e.g.*, *Hartford-Empire Co.* v. *United States*, *supra*, 323 U.S. at 409-410, 423, 431-432; *William R. Warner & Co.* v. *Eli Lilly & Co.*, *supra*, 265 U.S. at 532-533. Since a prohibition on copying even a nonfunctional feature of an article may impede competition or engender added marketing costs, it should be considered as a last resort and imposed only to the extent necessary to allow informed consumer choice. See, *e.g.*, *Kellogg Co.* v. *National Biscuit Co.*, *supra*, 305 U.S. at 122; *William R. Warner & Co.* v. *Eli Lilly & Co.*, *supra*, 265 U.S. at 532-533.[38]

As this Court has emphasized, "[f]ull disclosure gives the manufacturer all the protection to which he is entitled." *Champion Plug Co.* v. *Sanders*, 331 U.S. 125, 130 (1947). Appropriate labeling or packaging of a product is ordinarily sufficient to avoid consumer confusion, as the Second Circuit previously held in *Bose Corp.* v. *Linear Design Labs, Inc.*, 467 F.2d 304, 309-310 (1972). See *Kellogg Co.* v. *National Biscuit Co.*, *supra*, 305 U.S. at 119-120; *William R. Warner & Co.* v. *Eli Lilly & Co.*, *supra*, 265 U.S. at 532-533. In this case, the district court found that labeling of the capsules themselves would not be effective because the print necessarily would be too small to be legible to the average consumer. Nevertheless, even assuming a violation of Section 43(a), the injunction granted by the district court is excessive in two respects.

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[38] Because the record fails to support a finding of an intentional violation, the district court's award of money damages and profits should be reversed. 15 U.S.C. 1117; cf. 15 U.S.C. 1114(1)(b). See, *e.g.*, *Champion Plug Co.* v. *Sanders*, 331 U.S. 125, 131-132 (1947); *Metric & Multistandard Components Corp.* v. *Metric's, Inc.*, 635 F.2d 710, 715-716 (8th Cir. 1980); *Carl Zeiss Stiftung* v. *VEB Carl Zeiss Jena*, 433 F.2d 686, 706-708 (2d Cir. 1970), cert. denied, 403 U.S. 905 (1971). See also pages 16-22, *supra*.

First, as noted above, separate consideration must be given to relief in the institutional submarket, where capsule color identity is not likely to preclude informed choice by purchasers. Banning color copying in such a submarket is not necessary. Accurate labeling as to source, placed on the container in which pills are delivered to institutional customers, would be sufficient to satisfy all statutory requirements.

Second, the generic manufacturers should be given the opportunity to propose practical alternative remedies, such as prepackaging their products with their own labels for resale to consumers. See SRI International, *Pharmaceutical Industry Perspectives: A U.S. Generics Breakthrough?* 44, 55-56 (May 1980). Such action would allow generic manufacturers to avail themselves of any legitimate commercial advantages deriving from the capsule color of the brand name manufacturers, while preserving product identification features that are of value both to brand name manufacturers and consumers.

CONCLUSION

The decision of the court of appeals should be reversed and the case remanded for further consideration of respondent's claims under Section 43(a) of the Lanham Act.

Respectfully submitted.

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